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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/660,444

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Andrzej Chanduszeko

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EXAMINER

YABUT, DIANE D

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

05/06/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/660,444	Applicant(s) CHANDUSZKO ET AL.	
	Examiner DIANE YABUT	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31,34-37,40-42 and 60-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31,34-37,40-42 and 60-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to applicant's amendment received on 01/20/2009.

The examiner acknowledges the amendments made to the claims.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 31, 34-35, and 60-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Nobles** (U.S. Pub. No. **2002/0045908**) in view of **Ginn** (U.S. Patent No. **6,702,835**).

Claims 31, 34-35, and 60-63: Nobles discloses introducing into a heart of a patient a delivery member comprising at least a first flexible ("resilient") member **50** or **128** having a first end portion and arms **28** and **32** (first and second flexible members) at a second free end portion, and introducing said second free end portion through the opening of a patent foramen ovale **26** (page 6, paragraph 141) by entering the opening from one side, passing through the tunnel of the patent foramen ovale and exiting the opening of the patent foramen ovale on the opposite side prior to introducing a hole through a septal tissue **22**, contacting said first and second flexible members **28**, **32** on the opposite side of the septal tissue (Figure 4B), introducing a hole through the septal tissue from the one side to the opposite of the septal tissue, withdrawing said second

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free end portion of said flexible member from the opposite side (Figures 1-2, 15-16, 34-39). Nobles also discloses an apparatus ("patch") for joining tissue page 25, paragraph 351). After withdrawing the second free end portion of said flexible member, an occlusion device **880** or **890** may be introduced through the hole created by the septal tissue (paragraphs 314-320, Figures 72-73).

Although the flexible member is not spiral-shaped, it would have been obvious to one of ordinary skill in the art to modify Nobles with a spiral-shaped flexible member since coils, spirals, and helical configurations are well known shapes for elements that effectively approximate tissue.

Nobles discloses the claimed invention except for expressly disclosing introducing the delivery member from the right atrial side to a left atrial side, instead of from generally "one side" to the "opposite side" of septal tissue.

Ginn teaches delivering a delivery member to a patent foramen ovale from a right atrial side to the left atrial side (Figures 5A-8B; col. 7, line 60 to col. 8, line 9). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Nobles by introducing the delivery member from the right atrial side to a left atrial side, as taught by Ginn, since it was well known in the art for septal occluders to be effectively introduced percutaneously into a peripheral vein, such as a femoral or jugular vein, to be advanced through the vena cava into the right atrium and then advanced beyond the septum wall in the left atrium.

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3. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Nobles** (U.S. Pub. No. **2002/0045908**) in view of **Ginn** (U.S. Patent No. **6,702,835**), as applied to claim 35 above, and further in view of **Sawyer** (U.S. Patent No. **5,749,895**).

Claim 36: Neither Nobles nor Ginn expressly discloses using a tissue welding apparatus. However, use of a tissue welding apparatus is well known in the art, as evidenced by Sawyer (see abstract). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a tissue welding apparatus, as taught by Sawyer, to Nobles and Ginn in order to more effectively ensure a tight occlusion of the PFO defect.

4. Claims 37 and 40-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Nobles** (U.S. Pub. No. **2002/0045908**) in view of **Ginn** (U.S. Patent No. **6,702,835**) and **Das** (U.S. Patent No. **5,334,217**).

Claims 37 and 40-41: Nobles and Ginn disclose the claimed invention, as discussed in paragraph 3 above, except for the flexible members being hexagonally shaped.

Das teaches a septal closure device and method using flexible members **24C** being introduced into a patent foramen ovale, which are hexagonally shaped (Figure 5C). It would have been obvious to one of ordinary skill in the art at the time of invention to modify Nobles with Das, since it is also a closure method and the hexagonally shaped members provide bends which permit the frame to be collapsed more readily into a delivery catheter (col. 5, line 54 to col. 6, line 6).

5. Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Nobles** (U.S. Pub. No. **2002/0045908**) in view of **Ginn** (U.S. Patent No. **6,702,835**) and **Das** (U.S. Patent No. **5,334,217**), as applied to claim 41 above, and further in view of **Sawyer** (U.S. Patent No. **5,749,895**).

Claim 42: Nobles, Ginn, and Das do not expressly disclose using a tissue welding apparatus. However, use of a tissue welding apparatus is well known in the art, as evidenced by Sawyer (see abstract). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a tissue welding apparatus, as taught by Sawyer, to Nobles, Ginn, and Das in order to more effectively ensure a tight occlusion of the PFO defect.

Response to Arguments

6. Applicant's arguments with respect to claims 31, 34-37, 40-42, and 60-63 have been considered but are moot in view of the new ground(s) of rejection.

7. Applicant generally argues that none of the prior art of record discloses withdrawing the second free end portion of said flexible member from said left atrial side prior to introducing an occlusion device for occluding said patent foramen ovale through said hole in said septum primum, specifically Nobles because the suture **40** (previously cited as "the occlusion device") is introduced before the second free end portion of the flexible member is withdrawn, rather than afterwards. However, as maintained above, the examiner now cites **880** or **890** as the occlusion device which may be introduced through the hole created by the septal tissue after the flexible member second free end

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portion is withdrawn or retracted from one side of the septal tissue (paragraphs 314-320, Figures 72-73).

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/
Examiner, Art Unit 3734

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3734